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Strategic Change Management for AI Adoption in Clinical Trials

A One-Page Implementation Guide

Introduction

Clinical research has world-class technology but struggles with AI adoption. While competitors focus heavily on features and capabilities, they're missing the real opportunity. It's not only about what AI can do, it's also about creating the social enablers that bridge the gap between innovation and implementation. The organizations that address people and process challenges before technology deployment will fundamentally reshape clinical research. This is a short guide to the discovery-driven approach for AI adoption in clinical trials.

1 Foundation First: Strategy Before Change Management

Establish a robust AI strategy before diving into change management and user adoption efforts. Address organizational structure, skillset recombination, and regulatory hurdles first.

2 The Art to the Science of Implementation

Understanding Clinical Research Variation

Despite standardized terminology, incredible variation exists across:

- **Organization Types:** Pharma, CROs, site/patient recruitment vendors, technology providers
- **Processes:** Linear/waterfall, agile, lean, scrum
- **Tools:** EDC systems, eCOA/ePRO, devices/sensors/wearables, EMR/EHR, central labs, specialty vendors
- **Communication:** Email, meeting minutes, spreadsheets, issue tracking software (JIRA, Basecamp, Asana)
- **Role Scope:** Same titles can have vastly different responsibilities, cross-functional knowledge, and system access

Barriers Beyond Change Resistance

- Single studies can have ALL above elements in play simultaneously
- AI/LLM solutions may collapse tasks requiring multiple roles with different technical expertise
- Creates both skill gaps and workflow issues when deployed without considering larger terrain

3 Discovery Phase Framework

Document Exactly What Organizations Use For:

- **Data Collection:** Methods, systems, processes
- **Issue Management:** Tracking, escalation, resolution workflows
- **Analysis:** Tools, decision-making processes
- **Roles & Staff Augmentation:** Who does what, beyond titles

Design As-Is and To-Be Process Flows That:

- **Highlight Quick Wins:** Highest-value areas to attack first
- **Structure Tiered Change:** Focus on foundational elements at pace employees can absorb
- **Ensure Unified Direction:** All activities pursue single, well-defined end state

4 Strategic Implementation Approach

Phase 1

Comprehensive Assessment

- **Map** current operational complexity against roles and staff augmentation
- **Identify** where AI may collapse multi-role tasks
- **Address** fragmented skill sets across organizational boundaries

Phase 2

Foundation Building

- **Skillset Recombination:** Target specific job role weaknesses vs. broad AI training
- **Process Optimization:** Challenge existing inefficiencies (e.g., study startup processes)
- **Regulatory Reconsideration:** Evaluate dogma like double program validation in AI context

Phase 3

Managed Deployment

- **Structure** change in digestible tiers
- **Engage** all stakeholders, including CROs, as partners in the process to build alignment and shared ownership
- **Monitor** adoption pace to prevent overwhelming staff

5 Critical Success Factors

- ✓ **Discovery Before Deployment:** Understand operational reality before implementing change
- ✓ **Address Complexity:** Account for variation in “standardized” processes
- ✓ **Skill Enhancement:** Recombine fragmented skillsets rather than replace roles
- ✓ **Inclusive Planning:** Involve all parties in ecosystem to prevent conflicts
- ✓ **Tiered Strategy:** Foundational changes before user adoption

Technology is an enabler, but social enablers drive adoption. The gap exists due to lack of social enablers, not technology limitations.

Accelerate your clinical trial AI strategy with proven implementation frameworks. Visit us at saama.com.

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